TABLE 14.4-4

DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

(Page 1 of 7)

Lab: Madison
Biomarker: Acetonitrile (ng/mL)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	80.79, 80.79	80.79, 80.79	30.00, 30.00	485.63, 358.74	333.75, 156.88
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	462.893, 327.315	419.920, 242.441
	MEDIAN	NA	80.79	80.79	30.00	485.63	158.31
	MIN, MAX	NA, NA	80.79, 80.79	80.79, 80.79	30.00, 30.00	158.31, 812.94	30.00, 812.94
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	158.31, 812.94	30.00, 812.94
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	14	28	42	28	33	61
	MEAN, GEO MEAN	517.75, 416.67	239.87, 189.14	332.49, 246.10	177.94, 110.24	167.94, 85.07	172.53, 95.82
	SD, SE	345.651, 92.379	263.077, 49.717	317.864, 49.047	266.322, 50.330	305.640, 53.205	285.945, 36.611
	MEDIAN	451.31	180.93	217.11	107.85	88.30	90.49
	MIN, MAX	132.35, 1346.61	75.16, 1508.01	75.16, 1508.01	30.00, 1436.85	30.00, 1521.61	30.00, 1521.61
	5%, 95%	132.35, 1346.61	92.52, 386.20	99.48, 820.65	30.00, 431.13	30.00, 972.68	30.00, 513.74
	BLQ Values Included	1	0	1	7	7	14
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	30.00	30.00
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	103.87, 99.93	103.87, 99.93	138.68, 138.68	NA, NA	138.68, 138.68
	SD, SE	NA, NA	32.568, 18.803	32.568, 18.803	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	119.11	119.11	138.68	NA	138.68
	MIN, MAX	NA, NA	66.48, 126.03	66.48, 126.03	138.68, 138.68	NA, NA	138.68, 138.68
	5%, 95%	NA, NA	66.48, 126.03	66.48, 126.03	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (ng/mL)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	89.31, 89.31	89.31, 89.31	30.00, 30.00	227.56, 220.03	161.71, 113.25
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	82.095, 58.050	127.984, 73.891
	MEDIAN	NA	89.31	89.31	30.00	227.56	169.51
	MIN, MAX	NA, NA	89.31, 89.31	89.31, 89.31	30.00, 30.00	169.51, 285.61	30.00, 285.61
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	169.51, 285.61	30.00, 285.61
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	14	27	41	28	33	61
	MEAN, GEO MEAN	510.28, 412.18	336.97, 222.29	396.15, 274.46	169.87, 119.17	190.16, 112.33	180.85, 115.42
	SD, SE	377.538, 100.901	355.312, 68.380	367.841, 57.447	145.990, 27.589	207.435, 36.110	180.676, 23.133
	MEDIAN	408.20	213.74	273.08	112.33	92.04	97.19
	MIN, MAX	137.22, 1578.50	30.00, 1701.68	30.00, 1701.68	30.00, 688.37	30.00, 756.74	30.00, 756.74
	5%, 95%	137.22, 1578.50	48.66, 1002.96	60.93, 1002.96	30.00, 371.86	30.00, 664.01	30.00, 610.62
	BLQ Values Included	0	1	1	6	5	11
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	30.00	30.00
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	255.11, 197.09	255.11, 197.09	135.58, 135.58	NA, NA	135.58, 135.58
	SD, SE	NA, NA	231.994, 133.942	231.994, 133.942	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	128.83	128.83	135.58	NA	135.58
	MIN, MAX	NA, NA	113.65, 522.85	113.65, 522.85	135.58, 135.58	NA, NA	135.58, 135.58
	5%, 95%	NA, NA	113.65, 522.85	113.65, 522.85	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (ng/mL)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	67.97, 67.97	67.97, 67.97	257.61, 257.61	632.09, 333.69	507.26, 306.12
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	759.185, 536.825	578.727, 334.128
	MEDIAN	NA	67.97	67.97	257.61	632.09	257.61
	MIN, MAX	NA, NA	67.97, 67.97	67.97, 67.97	257.61, 257.61	95.26, 1168.91	95.26, 1168.91
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	95.26, 1168.91	95.26, 1168.91
	BLQ Values Included	NA	0	0	0	0	0
Caucasian	N	14	25	39	27	33	60
	MEAN, GEO MEAN	947.27, 596.12	406.49, 260.10	600.61, 350.30	207.49, 138.34	155.83, 111.98	179.08, 123.16
	SD, SE	949.748, 253.831	499.960, 99.992	731.792, 117.181	185.705, 35.739	144.188, 25.100	164.757, 21.270
	MEDIAN	405.61	239.93	291.67	132.65	109.58	120.18
	MIN, MAX	166.78, 2679.33	46.59, 2333.96	46.59, 2679.33	30.00, 722.48	30.00, 619.94	30.00, 722.48
	5%, 95%	166.78, 2679.33	76.49, 1389.35	76.49, 2441.49	30.00, 568.69	30.00, 568.52	30.00, 568.61
	BLQ Values Included	0	0	0	6	4	10
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	70.47, 70.47	70.47, 70.47
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	70.47	70.47
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	70.47, 70.47	70.47, 70.47
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	407.32, 311.33	407.32, 311.33	263.46, 263.46	NA, NA	263.46, 263.46
	SD, SE	NA, NA	346.497, 200.050	346.497, 200.050	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	301.72	301.72	263.46	NA	263.46
	MIN, MAX	NA, NA	125.91, 794.33	125.91, 794.33	263.46, 263.46	NA, NA	263.46, 263.46
	5%, 95%	NA, NA	125.91, 794.33	125.91, 794.33	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
(Page 4 of 7)

Lab: Madison
Biomarker: Acetonitrile (ng/mL)
Timepoint: Week 6

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	103.56, 103.56	103.56, 103.56	30.00, 30.00	591.40, 587.82	404.26, 218.04
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	91.804, 64.915	330.558, 190.848
	MEDIAN	NA	103.56	103.56	30.00	591.40	526.48
	MIN, MAX	NA, NA	103.56, 103.56	103.56, 103.56	30.00, 30.00	526.48, 656.31	30.00, 656.31
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	526.48, 656.31	30.00, 656.31
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	13	24	37	28	33	61
	MEAN, GEO MEAN	504.44, 409.09	428.77, 271.73	455.36, 313.74	213.30, 132.81	236.88, 141.84	226.05, 137.62
	SD, SE	251.277, 69.692	486.573, 99.321	416.710, 68.507	228.768, 43.233	235.314, 40.963	230.701, 29.538
	MEDIAN	537.13	216.20	298.89	115.51	150.96	124.87
	MIN, MAX	31.69, 1060.80	97.44, 1665.36	31.69, 1665.36	30.00, 886.61	30.00, 947.37	30.00, 947.37
	5%, 95%	31.69, 1060.80	103.47, 1460.56	97.44, 1460.56	30.00, 744.35	30.00, 670.92	30.00, 670.92
	BLQ Values Included	0	0	0	5	6	11
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	30.00	30.00
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	30.00, 30.00	30.00, 30.00
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	518.28, 190.04	518.28, 190.04	105.18, 105.18	NA, NA	105.18, 105.18
	SD, SE	NA, NA	769.524, 444.285	769.524, 444.285	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	99.35	99.35	105.18	NA	105.18
	MIN, MAX	NA, NA	49.12, 1406.38	49.12, 1406.38	105.18, 105.18	NA, NA	105.18, 105.18
	5%, 95%	NA, NA	49.12, 1406.38	49.12, 1406.38	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (ng/mL)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	85.41, 85.41	85.41, 85.41	86.90, 86.90	484.17, 432.44	351.75, 253.29
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	307.945, 217.750	316.264, 182.595
	MEDIAN	NA	85.41	85.41	86.90	484.17	266.42
	MIN, MAX	NA, NA	85.41, 85.41	85.41, 85.41	86.90, 86.90	266.42, 701.92	86.90, 701.92
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	266.42, 701.92	86.90, 701.92
Caucasian	N	15	28	43	28	33	61
	MEAN, GEO MEAN	613.58, 527.90	342.44, 274.61	437.02, 344.93	191.97, 167.37	187.70, 150.61	189.66, 158.08
	SD, SE	363.926, 93.965	236.963, 44.782	311.997, 47.579	102.308, 19.334	132.956, 23.145	118.923, 15.227
	MEDIAN	481.97	260.36	354.55	156.74	156.31	156.31
	MIN, MAX	210.12, 1398.07	82.80, 995.06	82.80, 1398.07	41.94, 452.37	30.00, 599.86	30.00, 599.86
	5%, 95%	210.12, 1398.07	86.83, 775.61	111.46, 1046.64	83.94, 382.95	44.47, 547.22	57.20, 395.22
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	40.12, 40.12	40.12, 40.12
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	40.12	40.12
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	40.12, 40.12	40.12, 40.12
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	321.15, 229.81	321.15, 229.81	160.73, 160.73	NA, NA	160.73, 160.73
	SD, SE	NA, NA	326.366, 188.428	326.366, 188.428	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	149.70	149.70	160.73	NA	160.73
	MIN, MAX	NA, NA	116.24, 697.51	116.24, 697.51	160.73, 160.73	NA, NA	160.73, 160.73
	5%, 95%	NA, NA	116.24, 697.51	116.24, 697.51	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (nmol/L)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1969.7, 1969.7	1969.7, 1969.7	731.4, 731.4	11839.6, 8746.2	8136.8, 3824.7
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	11285.40, 7979.95	10237.70, 5910.72
	MEDIAN	NA	1969.7	1969.7	731.4	11839.6	3859.6
	MIN, MAX	NA, NA	1969.7, 1969.7	1969.7, 1969.7	731.4, 731.4	3859.6, 19819.5	731.4, 19819.5
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	3859.6, 19819.5	731.4, 19819.5
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	14	28	42	28	33	61
	MEAN, GEO MEAN	12622.7, 10158.4	5847.9, 4611.2	8106.2, 6000.0	4338.3, 2687.7	4094.3, 2074.0	4206.3, 2336.0
	SD, SE	8426.97, 2252.20	6413.83, 1212.10	7749.53, 1195.78	6492.94, 1227.05	7451.50, 1297.14	6971.34, 892.59
	MEDIAN	11002.9	4411.1	5293.2	2629.3	2152.8	2206.1
	MIN, MAX	3226.7, 32830.4	1832.4, 36765.3	1832.4, 36765.3	731.4, 35030.4	731.4, 37096.9	731.4, 37096.9
	5%, 95%	3226.7, 32830.4	2255.6, 9415.6	2425.3, 20007.4	731.4, 10510.9	731.4, 23713.9	731.4, 12525.0
	BLQ Values Included	1	0	1	7	7	14
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	731.4	731.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2532.4, 2436.3	2532.4, 2436.3	3381.0, 3381.0	NA, NA	3381.0, 3381.0
	SD, SE	NA, NA	793.99, 458.41	793.99, 458.41	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2903.9	2903.9	3381.0	NA	3381.0
	MIN, MAX	NA, NA	1620.8, 3072.6	1620.8, 3072.6	3381.0, 3381.0	NA, NA	3381.0, 3381.0
	5%, 95%	NA, NA	1620.8, 3072.6	1620.8, 3072.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (nmol/L)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2177.4, 2177.4	2177.4, 2177.4	731.4, 731.4	5548.0, 5364.4	3942.4, 2761.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2001.47, 1415.25	3120.25, 1801.48
	MEDIAN	NA	2177.4	2177.4	731.4	5548.0	4132.7
	MIN, MAX	NA, NA	2177.4, 2177.4	2177.4, 2177.4	731.4, 731.4	4132.7, 6963.2	731.4, 6963.2
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	4132.7, 6963.2	731.4, 6963.2
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	14	27	41	28	33	61
	MEAN, GEO MEAN	12440.6, 10048.8	8215.3, 5419.4	9658.1, 6691.4	4141.5, 2905.5	4636.0, 2738.6	4409.0, 2814.0
	SD, SE	9204.37, 2459.97	8662.52, 1667.10	8967.97, 1400.56	3559.23, 672.63	5057.27, 880.36	4404.87, 563.99
	MEDIAN	9951.8	5211.0	6657.7	2738.5	2243.9	2369.5
	MIN, MAX	3345.4, 38483.8	731.4, 41487.0	731.4, 41487.0	731.4, 16782.5	731.4, 18449.3	731.4, 18449.3
	5%, 95%	3345.4, 38483.8	1186.3, 24452.2	1485.5, 24452.2	731.4, 9065.9	731.4, 16188.6	731.4, 14886.9
	BLQ Values Included	0	1	1	6	5	11
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	731.4	731.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	6219.6, 4805.0	6219.6, 4805.0	3305.4, 3305.4	NA, NA	3305.4, 3305.4
	SD, SE	NA, NA	5656.01, 3265.50	5656.01, 3265.50	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3140.9	3140.9	3305.4	NA	3305.4
	MIN, MAX	NA, NA	2770.8, 12747.1	2770.8, 12747.1	3305.4, 3305.4	NA, NA	3305.4, 3305.4
	5%, 95%	NA, NA	2770.8, 12747.1	2770.8, 12747.1	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (nmol/L)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1657.1, 1657.1	1657.1, 1657.1	6280.5, 6280.5	15410.2, 8135.3	12367.0, 7463.0
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	18508.90, 13087.80	14109.40, 8146.05
	MEDIAN	NA	1657.1	1657.1	6280.5	15410.2	6280.5
	MIN, MAX	NA, NA	1657.1, 1657.1	1657.1, 1657.1	6280.5, 6280.5	2322.4, 28498.0	2322.4, 28498.0
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	2322.4, 28498.0	2322.4, 28498.0
	BLQ Values Included	NA	0	0	0	0	0
Caucasian	N	14	25	39	27	33	60
	MEAN, GEO MEAN	23094.3, 14533.4	9910.2, 6341.3	14643.0, 8540.4	5058.6, 3372.7	3799.2, 2730.2	4365.9, 3002.6
	SD, SE	23154.90, 6188.40	12189.00, 2437.80	17841.10, 2856.86	4527.49, 871.32	3515.30, 611.93	4016.78, 518.56
	MEDIAN	9888.7	5849.5	7110.9	3234.0	2671.6	2930.0
	MIN, MAX	4066.1, 65322.1	1135.9, 56901.9	1135.9, 65322.1	731.4, 17614.1	731.4, 15114.1	731.4, 17614.1
	5%, 95%	4066.1, 65322.1	1864.8, 33872.4	1864.8, 59523.5	731.4, 13864.7	731.4, 13860.5	731.4, 13862.6
	BLQ Values Included	0	0	0	6	4	10
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1718.1, 1718.1	1718.1, 1718.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1718.1	1718.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1718.1, 1718.1	1718.1, 1718.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	9930.5, 7590.2	9930.5, 7590.2	6423.2, 6423.2	NA, NA	6423.2, 6423.2
	SD, SE	NA, NA	8447.60, 4877.23	8447.60, 4877.23	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	7355.9	7355.9	6423.2	NA	6423.2
	MIN, MAX	NA, NA	3069.7, 19365.8	3069.7, 19365.8	6423.2, 6423.2	NA, NA	6423.2, 6423.2
	5%, 95%	NA, NA	3069.7, 19365.8	3069.7, 19365.8	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Madison
Biomarker: Acetonitrile (nmol/L)
Timepoint: Week 6

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2524.8, 2524.8	2524.8, 2524.8	731.4, 731.4	14418.2, 14331.1	9855.9, 5315.8
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2238.13, 1582.60	8059.00, 4652.86
	MEDIAN	NA	2524.8	2524.8	731.4	14418.2	12835.6
	MIN, MAX	NA, NA	2524.8, 2524.8	2524.8, 2524.8	731.4, 731.4	12835.6, 16000.8	731.4, 16000.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	12835.6, 16000.8	731.4, 16000.8
	BLQ Values Included	NA	0	0	1	0	1
Caucasian	N	13	24	37	28	33	61
	MEAN, GEO MEAN	12298.1, 9973.5	10453.4, 6624.8	11101.6, 7648.9	5200.2, 3237.9	5775.0, 3458.0	5511.2, 3355.1
	SD, SE	6126.12, 1699.08	11862.70, 2421.45	10159.40, 1670.19	5577.37, 1054.02	5736.95, 998.68	5624.50, 720.14
	MEDIAN	13095.2	5271.0	7286.9	2816.0	3680.4	3044.3
	MIN, MAX	772.6, 25862.3	2375.6, 40601.5	772.6, 40601.5	731.4, 21615.6	731.4, 23096.9	731.4, 23096.9
	5%, 95%	772.6, 25862.3	2522.6, 35608.5	2375.6, 35608.5	731.4, 18147.3	731.4, 16357.0	731.4, 16357.0
	BLQ Values Included	0	0	0	5	6	11
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	731.4	731.4
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	731.4, 731.4	731.4, 731.4
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	12635.7, 4633.1	12635.7, 4633.1	2564.3, 2564.3	NA, NA	2564.3, 2564.3
	SD, SE	NA, NA	18761.00, 10831.70	18761.00, 10831.70	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	2422.2	2422.2	2564.3	NA	2564.3
	MIN, MAX	NA, NA	1197.5, 34287.5	1197.5, 34287.5	2564.3, 2564.3	NA, NA	2564.3, 2564.3
	5%, 95%	NA, NA	1197.5, 34287.5	1197.5, 34287.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Madison
Biomarker: Acetonitrile (nmol/L)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	2082.3, 2082.3	2082.3, 2082.3	2118.7, 2118.7	11804.0, 10542.8	8575.6, 6175.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	7507.78, 5308.80	7710.49, 4451.66
	MEDIAN	NA	2082.3	2082.3	2118.7	11804.0	6495.2
	MIN, MAX	NA, NA	2082.3, 2082.3	2082.3, 2082.3	2118.7, 2118.7	6495.2, 17112.8	2118.7, 17112.8
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6495.2, 17112.8	2118.7, 17112.8
Caucasian	N	15	28	43	28	33	61
	MEAN, GEO MEAN	14959.1, 12870.2	8348.5, 6695.0	10654.5, 8409.4	4680.3, 4080.5	4576.2, 3671.7	4624.0, 3854.0
	SD, SE	8872.54, 2290.88	5777.15, 1091.78	7606.51, 1159.98	2494.24, 471.37	3241.50, 564.27	2899.34, 371.22
	MEDIAN	11750.5	6347.3	8643.9	3821.2	3810.7	3810.7
	MIN, MAX	5122.7, 34085.0	2018.6, 24259.5	2018.6, 34085.0	1022.5, 11028.7	731.4, 14624.7	731.4, 14624.7
	5%, 95%	5122.7, 34085.0	2116.9, 18909.3	2717.3, 25517.1	2046.5, 9336.2	1084.1, 13341.3	1394.5, 9635.5
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	978.1, 978.1	978.1, 978.1
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	978.1	978.1
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	978.1, 978.1	978.1, 978.1
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	7829.6, 5602.7	7829.6, 5602.7	3918.5, 3918.5	NA, NA	3918.5, 3918.5
	SD, SE	NA, NA	7956.88, 4593.91	7956.88, 4593.91	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3649.6	3649.6	3918.5	NA	3918.5
	MIN, MAX	NA, NA	2833.8, 17005.3	2833.8, 17005.3	3918.5, 3918.5	NA, NA	3918.5, 3918.5
	5%, 95%	NA, NA	2833.8, 17005.3	2833.8, 17005.3	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: CCLS
Biomarker: Carboxyhemoglobin (% saturation)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.2, 3.2	3.2, 3.2	0.3, 0.3	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3.2	3.2	0.3	0.3	0.3
	MIN, MAX	NA, NA	3.2, 3.2	3.2, 3.2	0.3, 0.3	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4.4, 3.3	4.6, 3.6	4.5, 3.4	0.5, 0.4	0.3, 0.3	0.4, 0.4
	SD, SE	3.35, 0.79	3.06, 0.58	3.14, 0.46	0.20, 0.04	0.08, 0.01	0.16, 0.02
	MEDIAN	4.0	4.5	4.1	0.4	0.3	0.3
	MIN, MAX	0.3, 14.8	0.8, 11.4	0.3, 14.8	0.3, 1.0	0.3, 0.7	0.3, 1.0
	5%, 95%	0.3, 14.8	0.9, 11.3	0.9, 11.3	0.3, 0.8	0.3, 0.5	0.3, 0.7
	BLQ Values Included	1	0	1	11	25	36
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.3	0.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.3, 2.0	3.3, 2.0	0.7, 0.7	NA, NA	0.7, 0.7
	SD, SE	NA, NA	4.04, 2.33	4.04, 2.33	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.1	1.1	0.7	NA	0.7
	MIN, MAX	NA, NA	0.9, 8.0	0.9, 8.0	0.7, 0.7	NA, NA	0.7, 0.7
	5%, 95%	NA, NA	0.9, 8.0	0.9, 8.0	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACB
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Lab: CCLS
Biomarker: Carboxyhemoglobin (% saturation)
Timepoint: Week 2

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	5.3, 5.3	5.3, 5.3	0.3, 0.3	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	5.3	5.3	0.3	0.3	0.3
	MIN, MAX	NA, NA	5.3, 5.3	5.3, 5.3	0.3, 0.3	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	3.7, 2.7	4.2, 2.9	4.0, 2.8	0.4, 0.4	0.3, 0.3	0.4, 0.3
	SD, SE	2.69, 0.63	3.20, 0.62	2.99, 0.45	0.23, 0.04	0.05, 0.01	0.17, 0.02
	MEDIAN	3.0	3.7	3.4	0.3	0.3	0.3
	MIN, MAX	0.3, 8.6	0.3, 13.3	0.3, 13.3	0.3, 1.1	0.3, 0.5	0.3, 1.1
	5%, 95%	0.3, 8.6	0.3, 10.1	0.3, 9.8	0.3, 0.9	0.3, 0.5	0.3, 0.8
	BLQ Values Included	1	2	3	16	27	43
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.3	0.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.5, 1.9	3.5, 1.9	0.4, 0.4	NA, NA	0.4, 0.4
	SD, SE	NA, NA	4.45, 2.57	4.45, 2.57	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.1	1.1	0.4	NA	0.4
	MIN, MAX	NA, NA	0.7, 8.6	0.7, 8.6	0.4, 0.4	NA, NA	0.4, 0.4
	5%, 95%	NA, NA	0.7, 8.6	0.7, 8.6	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: CCLS
Biomarker: Carboxyhemoglobin (% saturation)
Timepoint: Week 3

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4.0, 4.0	4.0, 4.0	0.3, 0.3	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	4.0	4.0	0.3	0.3	0.3
	MIN, MAX	NA, NA	4.0, 4.0	4.0, 4.0	0.3, 0.3	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	17	25	42	28	33	61
	MEAN, GEO MEAN	4.7, 3.4	5.0, 4.3	4.9, 3.9	0.5, 0.4	0.5, 0.4	0.5, 0.4
	SD, SE	3.52, 0.85	2.61, 0.52	2.97, 0.46	0.48, 0.09	0.51, 0.09	0.49, 0.06
	MEDIAN	3.8	4.2	4.0	0.3	0.3	0.3
	MIN, MAX	0.3, 11.3	1.3, 9.7	0.3, 11.3	0.3, 2.8	0.3, 2.5	0.3, 2.8
	5%, 95%	0.3, 11.3	1.7, 9.3	1.3, 10.4	0.3, 1.0	0.3, 2.2	0.3, 1.0
	BLQ Values Included	1	0	1	14	20	34
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	1.6, 1.6	1.6, 1.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	1.6	1.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	1.6, 1.6	1.6, 1.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.2, 1.2	3.2, 1.2	0.3, 0.3	NA, NA	0.3, 0.3
	SD, SE	NA, NA	4.62, 2.67	4.62, 2.67	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.7	0.7	0.3	NA	0.3
	MIN, MAX	NA, NA	0.3, 8.5	0.3, 8.5	0.3, 0.3	NA, NA	0.3, 0.3
	5%, 95%	NA, NA	0.3, 8.5	0.3, 8.5	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: CCLS
Biomarker: Carboxyhemoglobin (% saturation)
Timepoint: Week 6

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	3.9, 3.9	3.9, 3.9	0.3, 0.3	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	3.9	3.9	0.3	0.3	0.3
	MIN, MAX	NA, NA	3.9, 3.9	3.9, 3.9	0.3, 0.3	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	13	24	37	28	33	61
	MEAN, GEO MEAN	4.9, 3.5	4.8, 3.9	4.8, 3.8	0.4, 0.4	0.4, 0.4	0.4, 0.4
	SD, SE	3.55, 0.99	2.51, 0.51	2.87, 0.47	0.21, 0.04	0.21, 0.04	0.21, 0.03
	MEDIAN	4.1	4.7	4.5	0.3	0.3	0.3
	MIN, MAX	0.3, 13.9	0.3, 9.8	0.3, 13.9	0.3, 1.1	0.3, 1.3	0.3, 1.3
	5%, 95%	0.3, 13.9	1.0, 8.9	0.3, 9.8	0.3, 0.9	0.3, 0.8	0.3, 0.8
	BLQ Values Included	1	1	2	11	20	31
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.3	0.3
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.5, 1.4	3.5, 1.4	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	4.97, 2.87	4.97, 2.87	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.8	0.8	0.5	NA	0.5
	MIN, MAX	NA, NA	0.4, 9.2	0.4, 9.2	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	0.4, 9.2	0.4, 9.2	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: CCLS
Biomarker: Carboxyhemoglobin (% saturation)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	4.1, 4.1	4.1, 4.1	0.3, 0.3	0.3, 0.3	0.3, 0.3
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.00, 0.00	0.00, 0.00
	MEDIAN	NA	4.1	4.1	0.3	0.3	0.3
	MIN, MAX	NA, NA	4.1, 4.1	4.1, 4.1	0.3, 0.3	0.3, 0.3	0.3, 0.3
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.3, 0.3	0.3, 0.3
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4.2, 3.2	4.6, 3.6	4.4, 3.5	0.5, 0.4	0.4, 0.4	0.4, 0.4
	SD, SE	3.00, 0.71	2.81, 0.53	2.86, 0.42	0.21, 0.04	0.18, 0.03	0.19, 0.02
	MEDIAN	3.6	4.2	4.0	0.4	0.3	0.4
	MIN, MAX	0.3, 12.2	0.6, 11.0	0.3, 12.2	0.3, 1.3	0.3, 1.1	0.3, 1.3
	5%, 95%	0.3, 12.2	0.9, 9.8	0.9, 9.8	0.3, 0.8	0.3, 0.9	0.3, 0.8
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.6, 0.6	0.6, 0.6
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.6	0.6
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.6, 0.6	0.6, 0.6
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	3.4, 1.7	3.4, 1.7	0.5, 0.5	NA, NA	0.5, 0.5
	SD, SE	NA, NA	4.53, 2.62	4.53, 2.62	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	0.8	0.8	0.5	NA	0.5
	MIN, MAX	NA, NA	0.7, 8.6	0.7, 8.6	0.5, 0.5	NA, NA	0.5, 0.5
	5%, 95%	NA, NA	0.7, 8.6	0.7, 8.6	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.15, 1.15	1.15, 1.15	0.51, 0.51	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.006, 0.003
	MEDIAN	NA	1.15	1.15	0.51	0.50	0.50
	MIN, MAX	NA, NA	1.15, 1.15	1.15, 1.15	0.51, 0.51	0.50, 0.50	0.50, 0.51
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.51
	BLQ Values Included	NA	0	0	0	2	2
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	4.79, 3.24	3.43, 2.60	3.97, 2.84	0.51, 0.50	0.68, 0.58	0.60, 0.54
	SD, SE	4.325, 1.019	2.680, 0.516	3.453, 0.515	0.023, 0.004	0.712, 0.124	0.527, 0.068
	MEDIAN	2.88	2.27	2.71	0.50	0.50	0.50
	MIN, MAX	0.50, 15.03	0.50, 10.41	0.50, 15.03	0.50, 0.62	0.50, 4.59	0.50, 4.59
	5%, 95%	0.50, 15.03	0.95, 9.39	0.87, 10.43	0.50, 0.53	0.50, 0.97	0.50, 0.77
	BLQ Values Included	1	1	2	26	24	50
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.50	0.50
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	2.07, 1.70	2.07, 1.70	0.50, 0.50	NA, NA	0.50, 0.50
	SD, SE	NA, NA	1.655, 0.955	1.655, 0.955	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	1.23	1.23	0.50	NA	0.50
	MIN, MAX	NA, NA	1.01, 3.98	1.01, 3.98	0.50, 0.50	NA, NA	0.50, 0.50
	5%, 95%	NA, NA	1.01, 3.98	1.01, 3.98	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)
Timepoint: Week 6

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.23, 1.23	1.23, 1.23	0.50, 0.50	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.000, 0.000
	MEDIAN	NA	1.23	1.23	0.50	0.50	0.50
	MIN, MAX	NA, NA	1.23, 1.23	1.23, 1.23	0.50, 0.50	0.50, 0.50	0.50, 0.50
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	BLQ Values Included	NA	0	0	1	2	3
Caucasian	N	14	24	38	28	33	61
	MEAN, GEO MEAN	4.70, 3.32	3.75, 2.56	4.10, 2.82	0.60, 0.55	0.60, 0.56	0.60, 0.55
	SD, SE	3.885, 1.038	3.366, 0.687	3.544, 0.575	0.398, 0.075	0.300, 0.052	0.346, 0.044
	MEDIAN	3.15	2.70	3.11	0.50	0.50	0.50
	MIN, MAX	0.50, 12.65	0.50, 13.54	0.50, 13.54	0.50, 2.46	0.50, 1.84	0.50, 2.46
	5%, 95%	0.50, 12.65	0.50, 9.83	0.50, 12.65	0.50, 1.35	0.50, 1.45	0.50, 1.35
	BLQ Values Included	1	2	3	26	29	55
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.50	0.50
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	1	1
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	22.78, 6.51	22.78, 6.51	0.50, 0.50	NA, NA	0.50, 0.50
	SD, SE	NA, NA	35.155, 20.297	35.155, 20.297	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.86	3.86	0.50	NA	0.50
	MIN, MAX	NA, NA	1.13, 63.34	1.13, 63.34	0.50, 0.50	NA, NA	0.50, 0.50
	5%, 95%	NA, NA	1.13, 63.34	1.13, 63.34	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	1	NA	1

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	1.19, 1.19	1.19, 1.19	0.51, 0.51	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.000, 0.000	0.006, 0.003
	MEDIAN	NA	1.19	1.19	0.51	0.50	0.50
	MIN, MAX	NA, NA	1.19, 1.19	1.19, 1.19	0.51, 0.51	0.50, 0.50	0.50, 0.51
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.51
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	4.62, 3.23	3.50, 2.60	3.94, 2.83	0.55, 0.53	0.64, 0.59	0.60, 0.56
	SD, SE	3.929, 0.926	2.849, 0.538	3.318, 0.489	0.204, 0.039	0.380, 0.066	0.312, 0.040
	MEDIAN	2.97	2.36	2.79	0.50	0.50	0.50
	MIN, MAX	0.50, 13.35	0.50, 11.98	0.50, 13.35	0.50, 1.48	0.50, 2.55	0.50, 2.55
	5%, 95%	0.50, 13.35	0.81, 9.34	0.81, 11.98	0.50, 0.99	0.50, 1.17	0.50, 1.09
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	0.50	0.50
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	0.50, 0.50	0.50, 0.50
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	12.43, 5.30	12.43, 5.30	0.50, 0.50	NA, NA	0.50, 0.50
	SD, SE	NA, NA	17.162, 9.908	17.162, 9.908	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	3.92	3.92	0.50	NA	0.50
	MIN, MAX	NA, NA	1.18, 32.18	1.18, 32.18	0.50, 0.50	NA, NA	0.50, 0.50
	5%, 95%	NA, NA	1.18, 32.18	1.18, 32.18	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calculating the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)
Timepoint: Week 1

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	25.67, 25.67	25.67, 25.67	3.22, 3.22	6.16, 6.14	5.18, 4.95
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	0.544, 0.385	1.738, 1.003
	MEDIAN	NA	25.67	25.67	3.22	6.16	5.77
	MIN, MAX	NA, NA	25.67, 25.67	25.67, 25.67	3.22, 3.22	5.77, 6.54	3.22, 6.54
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	5.77, 6.54	3.22, 6.54
	BLQ Values Included	NA	0	0	0	0	0
Caucasian	N	18	27	45	28	33	61
	MEAN, GEO MEAN	45.39, 37.62	28.92, 24.94	35.51, 29.40	6.37, 5.73	8.23, 7.40	7.37, 6.58
	SD, SE	27.734, 6.537	14.614, 2.812	22.135, 3.300	3.073, 0.581	4.163, 0.725	3.791, 0.485
	MEDIAN	38.12	25.56	31.63	5.39	6.84	6.76
	MIN, MAX	12.37, 100.50	5.35, 67.83	5.35, 100.50	2.90, 13.87	2.49, 23.25	2.49, 23.25
	5%, 95%	12.37, 100.50	5.37, 50.52	11.43, 87.23	3.12, 13.59	2.95, 17.37	3.12, 13.59
	BLQ Values Included	0	0	0	0	0	0
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	7.59, 7.59	7.59, 7.59
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	7.59	7.59
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	7.59, 7.59	7.59, 7.59
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	20.59, 16.87	20.59, 16.87	6.95, 6.95	NA, NA	6.95, 6.95
	SD, SE	NA, NA	15.965, 9.218	15.965, 9.218	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	14.50	14.50	6.95	NA	6.95
	MIN, MAX	NA, NA	8.56, 38.70	8.56, 38.70	6.95, 6.95	NA, NA	6.95, 6.95
	5%, 95%	NA, NA	8.56, 38.70	8.56, 38.70	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE
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Lab: Harrogate
Biomarker: Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)
Timepoint: Week 6

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	30.14, 30.14	30.14, 30.14	4.53, 4.53	8.65, 8.45	7.28, 6.86
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	2.645, 1.870	3.026, 1.747
	MEDIAN	NA	30.14	30.14	4.53	8.65	6.78
	MIN, MAX	NA, NA	30.14, 30.14	30.14, 30.14	4.53, 4.53	6.78, 10.52	4.53, 10.52
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.78, 10.52	4.53, 10.52
	BLQ Values Included	NA	0	0	0	0	0
Caucasian	N	14	24	38	28	33	61
	MEAN, GEO MEAN	44.70, 37.31	39.49, 34.49	41.41, 35.50	9.05, 7.96	8.84, 8.15	8.94, 8.06
	SD, SE	25.972, 6.941	18.608, 3.798	21.418, 3.474	5.411, 1.023	3.985, 0.694	4.654, 0.596
	MEDIAN	41.52	37.63	38.15	7.43	8.34	7.53
	MIN, MAX	9.56, 97.75	7.27, 90.32	7.27, 97.75	4.11, 27.86	4.09, 22.67	4.09, 27.86
	5%, 95%	9.56, 97.75	7.32, 73.92	7.32, 90.32	4.31, 20.64	4.36, 15.91	4.36, 16.50
	BLQ Values Included	0	0	0	0	0	0
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.23, 6.23	6.23, 6.23
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.23	6.23
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.23, 6.23	6.23, 6.23
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	NA	NA	NA	0	0
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	291.51, 90.67	291.51, 90.67	9.65, 9.65	NA, NA	9.65, 9.65
	SD, SE	NA, NA	448.166, 258.749	448.166, 258.749	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	45.44	45.44	9.65	NA	9.65
	MIN, MAX	NA, NA	20.28, 808.80	20.28, 808.80	9.65, 9.65	NA, NA	9.65, 9.65
	5%, 95%	NA, NA	20.28, 808.80	20.28, 808.80	NA, NA	NA, NA	NA, NA
	BLQ Values Included	NA	0	0	0	NA	0

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001

TABLE 14.4-4
DESCRIPTIVE STATISTICS OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT FOR DEMOGRAPHIC CHARACTERISTIC: RACE

Lab: Harrogate
Biomarker: Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)
Timepoint: Overall*

Characteristic	Statistic	Smokers			Non-Smokers		
		Male	Female	Overall	Male	Female	Overall
African American/Black	N	0	1	1	1	2	3
	MEAN, GEO MEAN	NA, NA	27.91, 27.91	27.91, 27.91	3.88, 3.88	7.41, 7.37	6.23, 5.95
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	1.054, 0.745	2.167, 1.251
	MEDIAN	NA	27.91	27.91	3.88	7.41	6.66
	MIN, MAX	NA, NA	27.91, 27.91	27.91, 27.91	3.88, 3.88	6.66, 8.15	3.88, 8.15
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	6.66, 8.15	3.88, 8.15
Caucasian	N	18	28	46	28	33	61
	MEAN, GEO MEAN	43.73, 36.74	33.29, 28.95	37.38, 31.78	7.71, 6.90	8.54, 7.92	8.16, 7.44
	SD, SE	25.307, 5.965	16.108, 3.044	20.595, 3.037	4.067, 0.769	3.787, 0.659	3.907, 0.500
	MEDIAN	41.27	32.62	34.25	6.49	7.24	7.06
	MIN, MAX	12.37, 99.13	6.31, 79.08	6.31, 99.13	3.62, 20.87	4.07, 22.96	3.62, 22.96
	5%, 95%	12.37, 99.13	6.35, 61.52	11.43, 79.08	3.83, 15.04	4.71, 16.35	4.07, 15.04
Native American	N	0	0	0	0	1	1
	MEAN, GEO MEAN	NA, NA	NA, NA	NA, NA	NA, NA	6.91, 6.91	6.91, 6.91
	SD, SE	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	NA	NA	NA	6.91	6.91
	MIN, MAX	NA, NA	NA, NA	NA, NA	NA, NA	6.91, 6.91	6.91, 6.91
	5%, 95%	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA	NA, NA
Other	N	0	3	3	1	0	1
	MEAN, GEO MEAN	NA, NA	156.05, 66.87	156.05, 66.87	8.30, 8.30	NA, NA	8.30, 8.30
	SD, SE	NA, NA	219.135, 126.517	219.135, 126.517	NA, NA	NA, NA	NA, NA
	MEDIAN	NA	42.07	42.07	8.30	NA	8.30
	MIN, MAX	NA, NA	17.39, 408.68	17.39, 408.68	8.30, 8.30	NA, NA	8.30, 8.30
	5%, 95%	NA, NA	17.39, 408.68	17.39, 408.68	NA, NA	NA, NA	NA, NA

* Overall values calculated by first averaging the results across visits within a subject, then calcularing the descriptive statistics across subjects. Count of BLQ values does not apply as the BLQ values were converted to the upper limit of the BLQ (e.g., '<1.234' will be used as '1.234') for the averages across visits within a subject thus eliminatig all BLQ values for the overall statistics.

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Source: https://www.industrydocuments.ucsf.edu/docs/lxnj0001